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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,577	06/28/2001	Shigefumi Sakai	210354US0	2545

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ALEXANDRIA, VA 22314

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/892,577

Applicant(s)

SAKAI ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/3/04, 3/31/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt is acknowledged of Amendment filed December 10, 2003. Claim rejections made under 35 U.S.C. § 112, first and second paragraphs as indicated in the previous Office action dated August 13, 2003 are withdrawn in view of the cancellation of claims. Claims 33-50 are pending.

#### ***Claim Rejections - 35 USC § 112***

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 50 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In this case, one of ordinary skill in the art would not reasonably apprise what would constitute a substantial size monodispersity. The metes and bounds of the limitation are not clear.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 35-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsaur et al. (US 5726138) ("Tsaur").

The claimed invention in Claim 33 is a composition comprising a hydrogel particles dispersed in an aqueous medium wherein each of said hydrogel particles comprises a non-crosslinked hydrogel having an oil component dispersed therein,

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wherein said hydrogel particles are prepared by a process comprising: providing an emulsion or dispersion of components comprising a non-crosslinked hydrogel-forming polymer, the oil component, and water; and discharging said emulsion or dispersion through an orifice under conditions sufficient to provide droplets, which are cooled after formation.

Claim 33 is a product-by-process claim. The court in In re Thorpe held, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). The court in In re Brown also held, “when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.” See 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). In this case, if a prior art teaches the same or obvious composition having the recited physical properties of the claimed composition, a rejection is proper. The requirement for the physical property limitation of the composition here means that the prior art composition should comprise hydrogel particles comprising a non-crosslinked hydrogel having an oil component dispersed therein, wherein the hydrogel particles are dispersed in an aqueous medium. The limitations in the dependent claims that are directed to the physical properties of the hydrogel particles, such as droplet

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shape and size, breaking intensity, ratio of longest/shortest diameters, etc. will be also considered. See instant claims 37, 39-50. However, the limitation on the process of making the claimed hydrogel-containing composition as recited in the base claim, Claim 33 are directed to process of making the composition which are viewed not patentably distinct from the prior art cited herein. Thus the process limitations in Claims 33-36, and 38 will not be considered.

Tsaur discloses aqueous compositions comprising hydrogel particles comprising water-insoluble skin benefit ingredients entrapped therein. See col. 2, line 63 – col. 3, line 60. The reference teaches that the benefit agent is dispersed in the hydrogel-forming polymers before the formation into hydrogel particles. See col. 4, lines 28 – 44; instant claim 41. Using surfactants in mixing the benefit agent and the hydrogel-forming polymer solution is also disclosed in col. 9, lines 6 – 24. See instant claim 41. The reference teaches using acrylic polymers such as Carbopol by B.F. Goodrich, polyvinyl alcohol, polyvinyl pyrrolidone, cationic guar, which meet the “polymer emulsifying or dispersing agent” limitation of instant claim 43. See col. 7, lines 48-65. The reference teaches an aqueous lotion composition with petrolatum, a solid fatty substance with m.p. 38-60°C, contained in a hydrogel particle comprising chitosan, a non-crosslinked, thermal gelatin. See Example 15; instant claims 42, 44, and 49. The diameter of the petrolatum hydrogel particles there is deemed to be 200 microns. See instant claim 37. Tsaur teaches to use two types of polymers to form hydrogel, wherein the first polymer may be thermal gelatin, such as agar or gelatins; and the second polymer is selected depending on the desired gel strength. See col. 5, line 56 – col. 6, line 22; instant claim 47. The reference further teaches that the gel strength can be manipulated by

controlling the amounts of the two polymers and the particle size. See col. 7, lines 33 – 40; col. 17, lines 44 – 57; instant claim 47.

Tsaur also teaches that the suitable benefit agents include waxes, ceramides, and pseudoceramides. See col. 8, lines 5 – 58; Examples 8-10; see instant claim 45.

Examiner interprets the limitation of Claim 46 to mean that more than or equal to 80 % of the hydrogel gel particles in the composition have substantially spherical shape, so that the ratio of the longest diameter/shortest diameter of a single gel particle is less than or equal to 1.7. While the Tsaur reference does not explicitly teach the recited ratio of the instant claim, examiner notes that that the reference teaches a single value of gel sizes measured for each illustrated formulation. See, for example, Table 12. See instant claim 50. Examiner also notes that Tsaur teaches in col. 4, lines 36 – 44, that “[t]he hydrogel precursor solution containing the dispersed benefit agent. . . is then added or injected to and mixed with an appropriate aqueous solution under such condition that the hydrogel dispersion precursor becomes insoluble . . . upon contact with the aqueous solution to form spherical, noodle shaped or in some cases irregular shaped hydrogel domains uniformly dispersed in said aqueous solution.” (Emphasis intentionally inserted). Thus, spherical shaped hydrogel particles are also taught by the reference. See instant claim 40.

While the Tsaur reference fails to illustrate a hydrogel particle formed with agar, as in instant claim 48, examiner notes that it is prima facie obvious to substitute equivalents known for the same purposes so long as the equivalency is recognized in the prior arts. See MPEP § 2144.06. The gel strength of agar is viewed an inherent property of the compound.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the illustrated inventions in Tsaur by substituting the hydrogel polymers used there with another conventional gelling agent such as agar as motivated by the teachings therein because of the expectation of successfully producing a similar composition.

### ***Response to Arguments***

Applicant's arguments filed December 11, 2003 have been fully considered but they are not persuasive.

While applicants distinguish the Tsaur invention as hydrogel particles having irregular shapes as produced by the sheer mixing elongated soft hydrogel noodles, examiner respectfully notes that the referred process and the produce made therefrom in the prior art is a mere preferred embodiment. The reference clearly teaches in col. 4, lines 48-53 "a continuous process such as a two fluid coextrusion nozzle", which is viewed an equivalence to producing droplets through orifice. The injection/low sheer mixing process, on the other hand, are "preferred" in the Tsaur patent. See col. 4, lines 64 – 66.

It is well settled in patent law that even a nonpreferred embodiment constitutes a prior art. See MPEP § 2123. The court in Merck & Co. v. Biocraft Laboratories held that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. See 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Particularly, the court in In re Gurley held, "[a] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other

product for the same use.” See 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

In this case, the reference teaches the method of producing hydrogel particles from a two fluid coextrusion nozzle, which, in examiner’s view produces reasonably same spherical shape of hydrogel particles as produced by applicants’ orifice. The fact that Tsaur prefers other shape of hydrogel particles does not render a well-known or obvious type of spherical hydrogel particles patentable.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

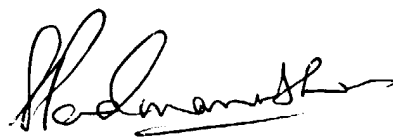


The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**